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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,826	01/17/2001	Nancy Tommye Jordan	03073.0001U2	8834

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NEEDLE & ROSENBERG P C
127 PEACHTREE STREET N E
ATLANTA, GA 30303-1811

EXAMINER

CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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1641

10

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/765,826

Applicant(s)
Jordan et al

Examiner
Chris L. Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 4, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) 1-4, 9, 10, and 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II - claims 5-8 and 11-14 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the Examiner has not shown the existence of independent and distinct inventions in all the claim groupings or that a serious burden would result if all the claims were examined together. This is not found persuasive because the grouping of claims are distinct and independent for the reasons set forth in the restriction requirement. The search for each invention in the grouped claims would require a different search strategy involving different search terms on commercial data bases and thus produce a burden on the examiner to search all of the claims.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 U.S.C. § 112

2. Claims 5-8 and 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague. Although the preamble of the claim recites a method for detecting conception in an animal, the body of the claim fails to recite a complete method of detection. The body of claim 1 only recites a step for detecting the presence of early conception factor in a body

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fluid of the animal. There is no step for contacting the body fluid with the appropriate reagents for detection of the early pregnancy factor and no correlation step that relates the detection of early pregnancy factor to conception in the animal which is the purpose of the method recited in the preamble.

Claim 11 is vague. In part (c), the recitation of “the antibody-early conception factor complexes” lacks antecedent support.

Claim 13 is vague.. In lines 3-4, the recitation of “the receptacle” lacks antecedent support. Claim 13 is further vague because it recites the use of a substrate or inducer but lacks an enzyme (or other reagent as the “detectable moiety”) to react with the substrate or inducer to generate a “detectable change” that is monitored. If the “detectable moiety” is an enzyme, claim 13 is incomplete since it lacks a separation that removes unbound “detectable moiety”. The lack of such a separation step would produce a positive result whether the early conception factor is present or not in the sample.

Claim 14 is incomplete because it lacks a separation step to remove unbound alkaline phosphatase, horseradish peroxidase, or urease if these enzymes are the conjugated to the antibodies. The lack of such a separation step would produce a positive result whether the early conception factor is present or not in the sample.

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Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the — basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 5, 6, 11, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Morton et al.

Morton et al (WO 86/05498) discloses various immunoassay methods for detecting pregnancy in animals by detecting the presence of early pregnancy factor (i.e. early conception factor) in serum. The various immunoassay methods utilize antibodies on solid phases alone or in combination with enzyme labeled antibodies to detect the early pregnancy factor/early conception factor (see pages 6-8).

5. Claims 5-8 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Jordan et al.

Jordan et al (WO 99/39208) disclose various immunoassay methods for the detection of early conception factor in serum, urine, or milk samples from animals. The methods utilize antibodies specific for the early conception factor labeled with enzymes, such as horseradish peroxidase or alkaline phosphatase, or colloidal gold (see pages 5-7).

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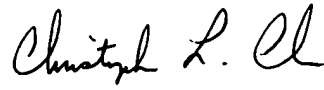
Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
May 19, 2003


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641